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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,554

03/15/2006

Jeremy Marshall

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,554	<b>Applicant(s)</b> MARSHALL ET AL.	
	<b>Examiner</b> KATHLEEN SONNETT	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-13 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 and 13 is/are allowed.
- 6) ☒ Claim(s) 1-7, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1 and 2** are rejected under 35 U.S.C. 102(b) as being anticipated by Fritz et al. (US 2002/0120216, "Fritz", now US 6,616,616). Fritz discloses a lancet comprising a body having a drive head (6) at one end and a projecting needle (5) at an other end, the body having two integral webs (see 7 in figs. 1a, 1b) projecting down both sides towards the location of a tip of the projecting needle, the webs being of undulating form when in a relaxed condition and of a flexible material so as to act as a spring to return the lancet to a retracted position.
3. Regarding claim 2, the undulations of the two webs (on either side of the drive head) are out of phase with one another.

### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-6 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (US 4,203,446; "Hofert") in view Kirk et al. (US 4,860,740; "Kirk"). Hofert discloses a lancet device comprising a casing and a lancet supported for reciprocatory movement in the casing between a cocked position and an advanced position, the lancet having a drive head (for

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example, 16) at one end and a projecting needle (12) at the other end, and a drive spring (36) positioned between the casing and the drive head of the lancet to drive the lancet and projecting needle into an advanced position in which the needle performs a pricking operation. Hofert also discloses a return spring (20) but does not disclose that this return spring is formed from two integral webs of undulating form and resilient material which project down both sides toward the needle tip.

6. However, Kirk teaches that it is well known to use two undulating web members (40) projecting down both sides of a medical device as a return spring to bias a portion of the device to its raised portion within a casing (fig. 1; col. 7 ll. 8-13). It would have been obvious to include such web members as a return spring instead of the coiled return spring (20) disclosed by Hofert because such a modification can be considered a simple substitution of one known spring mechanism for another where there is a reasonable expectation of success. One skilled in the art has good reason to pursue the known options within his or her technical grasp including various spring mechanisms. If this leads to the anticipated success, it is likely the product of ordinary skill and common sense.

7. Regarding claim 2, see fig. 1.

8. Regarding claim 6, Hofert discloses a movable rib (30) of the casing and a flexible button (40) on the casing which is movable to release the rib from the drive head to enable the drive spring to drive the lancet forwards. Hofert discloses the rib fitting into a recess (28) within the drive head. However, it would have been well within the purview of one skilled in the art to instead use a flange on the drive head upon which the rib rests instead of a recess on the drive head into which the rib fits since such a configuration would work in generally the same manner with the same result and it appears that a flange offers no advantage over the recess disclosed by Hofert.

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9. Regarding claims 3, 4, and 10, although Hofert fails to disclose a removable protective cap, such a cap is very well known in the art as are breakable connecting parts between a cap and the remainder of a lancet device.

10. **Claims 7 and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert in view of Kirk as applied to claims 5 and 6 above, and further in view of Tavel (US 3,375,381). Hofert in view of Kirk discloses the invention substantially as stated above and it would have been obvious to add a cap, also discussed above, in order to protect the user from accidental contact with the lancet needle as well as protecting the needle from contamination prior to use as is very well known in the art. Tavel teaches a connection between a cap and a casing of a device which includes a cap (12) that locates over flanges (raised surface above grooves 17 as viewed in fig. 1 which abuts bosses 16) on the casing, but can be twisted out of contact with the flanges to enable the cap to be removed to expose the casing. In particular, the cap may be twisted so that bosses (16) are twisted out of contact with (17) and aligned with channel (18) (col. 2, ll. 15-38) so that the cap may be removed. It would have been obvious to use the mechanism taught by Tavel to releasably connect a cap with the casing of Hofert as modified by Kirk in order to avoid accidental removal of the cap.

***Allowable Subject Matter***

11. Claims 12 and 13 are allowed.

***Response to Arguments***

12. Applicant's arguments with respect to the rejection of claims 1, 3, and 4 as being anticipated by Teo et al. (US 6,540,763; "Teo") have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendment to claim 1. In view of the amendments, claims 1 and 2 have been rejected as being anticipated by Fritz.

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13. Applicant's arguments with respect to the rejection of claims 1-6 and 10 as being unpatentable over Hofert in view of Kirk have been fully considered but they are not persuasive. In response to applicant's argument that Hofert and Kirk are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Kirk discloses a spring means to return a member from a depressed configuration to a relaxed configuration. Hofert similarly contains a spring means to return a member from a depressed configuration to a relaxed configuration. One skilled in the art would recognize that the spring means taught by Kirk finds merit in other medical devices that would use some sort of return spring mechanism other than powder inhalation devices.

14. In response to applicant's argument that there is no suggestion to combine the references, the examiner maintains that modifying Hofert by substituting its return spring for the spring mechanism of Kirk can be considered a simple substitution of one known spring mechanism for another with the predictable result of the undulating webs temporarily compressing while the lancet protrudes from the body before returning to their relaxed position to bias the lancet away from the opening in the casing. The return spring of Hofert is compressed when the lancet moves distally and then relaxes to its original configuration to return the lancet to its original position. The spring mechanism taught by Kirk similarly is compressed when the user closes cover (28) and when relaxed (after cover is opened), returns to its original position. Applicant points out that the spring of Kirk serves to force a capsule out of the casing when in the relaxed position whereas the spring of Hofert serves to return the lancet within the body in the relaxed position. However, both springs serve the same purpose of

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returning a portion of a medical device to its original position after it has been depressed by the user. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

15. Applicant's arguments regarding claim 12 have been considered and found persuasive. Claim 13 was mistakenly not addressed in the previous office action. However, due to its dependency on claim 12, it is allowable and its accidental omission from the previous office action has not affected the finality of this office action.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 8/20/2009

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
8/20/09